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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,686	11/10/2003	Leif N. Bowman	047711-0331	4638
23392	7590	11/30/2005	EXAMINER	
FOLEY & LARDNER 2029 CENTURY PARK EAST SUITE 3500 LOS ANGELES, CA 90067			STIGELL, THEODORE J	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/705,686

Applicant(s)

BOWMAN ET AL.

Examiner

Theodore J. Stigell

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☒ Claim(s) 24-28, 31-33 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment***

#### ***Specification***

The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see **MPEP 2181** (Rev. 1, Feb.2000))

Appropriate correction is required.

#### ***Claim Objections***

Claims 24-28 are objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner has objected to the claims for the reasons set forth above in the objection to the specification.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell (5,545,143).

Fischell clearly discloses an infusion set that includes all of the limitations as recited in claims 1. See Figures 10-17 and the respective portions of the specification. Fischell discloses an infusion set that includes a base (210) for providing an infusion path, the base having a first adhesive surface (232) that faces the skin surface of a user when the base is supported on the skin surface and when the infusion set is used to pass fluids to the user, a cannula (227) attached to the base (210), a removable connector (240) and tubing (243) attached to the base, wherein a contiguous passage for passing fluids is formed from the tubing to the cannula when the connector is removably attached to the base. The infusion set further includes a hub (250) removably affixable to the base and a needle (251) attached to the hub, the needle being removably insertable into the cannula. The base has a barrier (202) extending away from the surface of the base and the connector has at least stops (246) extending

away from the surface of the connector wherein the barrier restricts movement of the stop when the connector is rotated about the base. If the connector is rotated about an axis that is perpendicular to said first surface with enough force the stops can conceivably break and the connector would be rotatable to any degree between 0 and 360. It is the position of the Examiner that the inherent use of the device disclosed by Fischell et al. would meet all the limitations of the method claims disclosed by the Applicant.

In regards to claims 29-30, Fischell et al. clearly disclose all of the limitations. Fischell et al. disclose an infusion set comprising a base, a cannula, a tube affixed to the connector, and a connector removably attachable to the base in any one of at least two different positions (the connector can be attached the opposite way as it shown in Figure 13), the connector being rotatable on the base with enough force applied, and each connection position allowing for different possible relative orientations of the connector with respect to the base. The base comprising at least two barriers (opposite sides of 202) that are spaced around the base and wherein the connector comprises a stop (246) preventing rotation when it comes in contact with the barriers.

Claims 1-3,5-17,19-29 rejected under 35 U.S.C. 102(e) as being anticipated by Douglas et al. (6,685,674). Douglas et al. disclose an infusion set that includes all of the limitations as recited in independent claims 1,10,15, 24, and 29. Douglas et al. disclose a base (14,18,12) for providing an infusion path, the base having a first adhesive surface that faces a skin surface of a user when the base is supported on the skin surface and when the infusion set is used to pass fluids to the user, a cannula (22)

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connected to and extending away from the base, a connector (40) removably attachable to the base, and a tube (50) attached to the connector, wherein the connector is rotatable on the base to any degree the user prefers between 0 and 360 when the connector is removably attached to the base and wherein a contiguous passage for passing fluids is formed from the tubing to the cannula when the connector is removably attached to the base. The base comprises a barrier (17) and the connector comprises a stop (17). The infusion set also includes an attachable hub (32).

#### ***Allowable Subject Matter***

Claims 31-33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Response to Arguments***

Applicant's arguments filed September 29, 2005 have been fully considered but they are not persuasive.

In response to applicant's argument that Fischell et al. does not disclose a connector that is rotatable to more than 5 degrees, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is the position of the Examiner that connector disclosed by Fischell et al. could conceivably rotate more than five degrees if enough force was applied.

#### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 2005/0020972 to Horisberger et al. discloses an infusion set with a rotatable connector that is removably attachable to the base.

US 2005/0101933 to Marrs et al. discloses a subcutaneous infusion set with a removably attachable connector.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Theodore J. Stigell

  
NICHOLAS D. LUCCHESI  
SUPERVISORY PATENT EXAMINER  
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